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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/950,052	09/12/2001	Josef Pitha		9900

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EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/950,052

Applicant(s)

PITHA ET AL.

Examiner

Ralph Gitomer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The response received 7/26/04 has been entered and claims 1-8 are considered here. No claims have been amended or canceled. It is noted that claims 2 and 8 may be substantial duplicates.

Please update the specification regarding related applications. Also please inform the examiner as to how this CIP differs from the parent to determine the proper priority date. Priority is granted to 9/12/01 at this time.

The title of the invention is not directed to the presently claimed invention. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Applicants admissions.

The claims are directed toward obtaining beneficial results by administering a composition containing a compound which blocks the use of glucose. The specification discloses administering each of the compounds claimed for blocking the use of glucose and provides journal citations each of which was published at least a year before applicant's effective filing date as evidentiary proof. In the event that there is a definite

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correlation between blocking the metabolism of glucose and a beneficial biological result, then this is an inherent property of administering a compound that blocks the use of glucose.

Applicant's arguments filed 7/26/04 have been fully considered but they are not persuasive.

Applicants argue that the agents as claimed for obtaining benefits are not suggested.

It is the examiner's position that the present specification teaches on page 5 first paragraph, 5-thiogluco^{se} was administered to a rat. Also on page 5 3-O-methylglucose and 1,5-anhydro-D-glucitol have been administered. On page 7 first paragraph 2,5-anhydro-D-mannitol metabolism has been studied. Effects of each of these compounds have been studied. As no specific benefits are claimed, the effects may be beneficial in certain situations.

Claims 1, 2, 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Nutrition Reviews.

Nutrition Reviews entitled "Absorption and Effect of Ingested Mannoheptulose" teaches on page 206, the capacity of mannoheptulose to induce temporary hyperglycemia is known. The secretion and synthesis of insulin is inhibited by mannoheptulose. On page 207 mannoheptulose may be a therapeutic agent for treating hypoglycemic conditions.

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Applicant's arguments filed 7/26/04 have been fully considered but they are not persuasive.

Applicants argue that the reference does not teach beneficial biological results seen in caloric restriction, only treating hypoglycemia.

It is the examiner's position that present claim 1 states the composition is sufficient to lower tissue glucose level. The reference teaches treating inducing temporary hyperglycemia which would also then lower glucose levels. No beneficial biological results are claimed.

Claims 1, 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Francesconi.

Francesconi (Am J Physio) entitled "5-Thio-D-Glucose: Hypothermic Responses in Mice" teaches in the abstract, administering 5-thio-D-glucose with reduced availability of tissue glucose.

Applicant's arguments filed 7/26/04 have been fully considered but they are not persuasive.

Applicants argue that the reference does not teach beneficial biological results.

It is the examiner's position that the reference teaches the same compound as claimed to reduce availability of tissue glucose which would relate to beneficial biological results in general in some situations.

Claims 1, 6, 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakata.

Sakata (Am J Clin Nutr) entitled "Feeding Modulation by Pentose and Hexose Analogues" teaches on page 275S administering 2,5-anhydro-D-mannitol and feeding behavior observed. On page 276S column 1 it has been reported that peripheral administration of 2,5-AM decreases plasma glucose because of its inhibitory action on gluconeogenesis.

Applicant's arguments filed 7/26/04 have been fully considered but they are not persuasive.

Applicants argue that the reference does not teach beneficial biological results from caloric restriction.

It is the examiner's position that Sakata teaches the same compound as presently claimed decreases glucose levels.

All of the features of the claims are taught by each of the above references for the same function as claimed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988).

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative compounds claimed.
2. Amount of direction or guidance presented is insufficient to predict which substances encompassed by the claims would work.
3. Presence of working examples are only for a single specific substance and extension to other compounds has not been specifically taught or suggested.
4. The nature of the invention is complex and unpredictable.
5. State of the prior art indicates that most related substances are not effective for the claimed functions.
6. Level of predictability of the art is very unpredictable.
7. Breadth of the claims encompasses an innumerable number of compounds.
8. The level of one of ordinary skill in this art is variable.

The present invention would require a great deal of time and expense by a skilled artisan to study the effects of administering the compounds contemplated to obtain some biological results especially given that there are no criteria offered in the

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specification as to how to gauge the results of the administering. The specification does not offer any working examples which show the results obtained by the administration of compounds which block use of glucose in any controlled fashion. Avocado meal is likely to contain large amounts of fat which would change glucose metabolism. The specification appears to show that it is well known that the compounds of interest (i.e. 2-deoxy-D-glucose; 5-thio-D-glucose; 3-O-methylglucose; 1,5-anydro-D-glucitol; 2,5-anydro-D-mannitol and mannoheptulose) can block the use of glucose in cells to raise blood glucose levels and lower body temperature.

Applicant's arguments filed 7/26/04 have been fully considered but they are not persuasive.

Applicants argue that dosages are taught in the specification and a preferred agent is disclosed.

It is the examiner's position that no criteria are presented as to how to gauge the results of the administering. The specification only teaches that the compounds claimed can block the use of glucose in cells to raise blood glucose levels and lower body temperature. This would be insufficient to then obtain beneficial biological results as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 1 the method steps must be positively recited as gerunds, for example "comprising administration" may be intended to be "comprising administering". In claim 5 "androsugar" is queried.

This application contains claims 9-14 drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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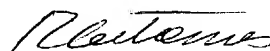
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Shimada (Sangyo Igaku) teaches the significance of 1,5-anhydro-D-glucitol in diabetes management.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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